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EXAMINER

KUBELIK, ANNE R

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 07/02/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,349

Applicant(s)

ROHDE ET AL.

Examiner

Anne R. Kubelik

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. As requested in Paper No. 11, filed 11 April 2003, claims 10-27 have been cancelled, and claims 28-37 have been added. Claims 28-37 are pending.
2. The substitute specification filed 18 June 2003 has been entered. All references to page numbers in this action (and in Applicant's response filed 11 April 2003) are to the page numbers of the substitute specification.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

4. The rejections of claims 10-27 under 35 U.S.C. 102(b) as being anticipated by each of Tacke et al (1996, Nature Biotechnol. 14:1597-1601) and Herbers et al (1997, Plant J. 12:1045-1056) taken with the evidence of Tacke et al are WITHDRAWN in light of amendment to the claims.

Claim Rejections - 35 USC § 112

5. Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing potato plants that are tolerant of drought, fungal infection and salt by transformation with a nucleic acid encoding the pr17 protein operably linked to an N-terminal extension of SEQ ID NO:1, does not reasonably provide enablement for a method of producing plants that are tolerant of temperature extremes by transformation with that nucleic acid or other derivatives of pr17 or a method of using a multitude of DNA molecules

Art Unit: 1638

that encode a "virus-encoded transport protein" to produce any and all plant species that are tolerant of drought, fungal infection, salt and temperature. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 September 2002, as applied to claims 10-27. Applicant's arguments filed 11 April 2003 have been fully considered but they are not persuasive.

Applicant urges that support for claims reciting increased tolerance to extreme temperature is found on pg 3 of the specification (response pg 7).

This is not found persuasive because the specification provides no evidence that plants transformed with pr17 or any other virus-encoded transport protein are tolerant to extreme temperatures. Applicant is invited to submit a Declaration providing data showing this.

Applicant urges that the specification teaches multiple transformation methods that allow one to transform various plant species, and the specification teaches the transformation of a plant with a nucleic acid encoding p17. Furthermore, Applicant urges that pr17 of PLRV is analogous to the movement protein of barley yellow dwarf luteovirus, taught by Tacke et al. Applicant urges that one of skill in the art would know that PLRV is an appropriate model system since PLRV belongs to luteoviruses that infect both dicots and monocots (response pg 8-9).

This is not found persuasive because the claims are not limited to transformation with a nucleic acid encoding pr17. Furthermore, as discussed in the prior Office action, Tacke et al teach that potato plants transformed with a nucleic acid encoding wild-type pr17 or pr-17 with an N-terminal extension other than SEQ ID NO:1 were not resistant to potato virus X (pg 1596,

Art Unit: 1638

paragraph spanning the columns). This result suggests that given the specificity of protein-protein interactions, it is unclear that a nucleic acid encoding pr17 + SEQ ID NO:1 would work in other plants. Applicant is invited to submit a declaration showing that a monocot transformed with a nucleic acid encoding pr17 is tolerant of drought, fungal infection, salt and temperature.

The instant specification also fails to provide guidance for isolation or synthesis of nucleic acids encoding other derivatives of pr17 or other virus-encoded transport proteins and fails to provide guidance for using those nucleic acids to produce plants that are tolerant of drought, fungal infection, salt and temperature.

Thus, the specification is not enabled for use of any nucleic acid other than the one encoding pr17 operably linked to SEQ ID NO:1 to produce plants that are tolerant of drought, fungal infection, or salt or for use of any nucleic acid to produce plants that are tolerant of temperature extremes.

6. Claims 28-37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 September 2002, as applied to claims 10-15 and 17-27. Applicant's arguments filed 11 April 2003 have been fully considered but they are not persuasive.

Applicant urges that the structural and physical characteristics of p17 are disclosed in the specification on pg 8, and the specification on pg 8 discloses that expression of wild-type and mutant PLRV-TPs confers resistance to viruses and increases sugar and starch concentrations.

Art Unit: 1638

Applicant argues that the specification thus describes the distinguishing structural features of the nucleic acids (response pg 9).

This is not found persuasive because the specification does not describe the structural features of DNA molecules that encode viral transport proteins other than PLRV p17 or hydrophilic N-terminal extensions other than SEQ ID NO:1. Because the sequences are not described, the method of using the sequences is not described. Thus, the specification does not describe the invention within the full scope of the claims.

7. Claims 28-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 September 2002, as applied to claims 10-27. Applicant's arguments filed 11 April 2003 have been fully considered but they are not persuasive.

The term "increased" in claim 28 is a relative term that renders the claim indefinite. The term "increased" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The change in salt concentration or tolerance should be compared to a known standard.

Applicant urges that "increased salt tolerance" is defined on pg 4 and that absolute "increased" salt concentration differs for different plants. Applicant urges that "increased tolerance to drought" would be understood by one reading the specification, for example,

Art Unit: 1638

example 5, Table 1 and figures 3-4. Applicant urges that "increased tolerance to fungal infections" would be understood by one reading the specification, for example, examples 4 and 6, and figures 5-6. Applicant urges that the specification thus provides measurements of wild-type plants as a known standard (response pg 10).

This is not found persuasive. The comparison to wild-type plants should be recited in the claims. The definition of "increased salt tolerance" on pg 4 is relative because it refers to "reduced growth", without a definition of the term. Thus, the phrase is not clearly defined. "Increased tolerance to drought" and "increased tolerance to fungal infections" cannot be defined by inference, because they are relative terms. A comparison for all recitations of "increased" in the claim to wild-type or plants not transformed with the nucleic acid encoding the virus-encoded transport protein would obviate this rejection.

The term "extreme" in claim 28 is a relative term that renders the claim indefinite. The term "extreme" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What temperature is considered extreme is unclear.

Applicant urges that the term "extreme temperature" is presented on pg 1 of the specification and is clarified by the phrase "i.e. cold and/or heat" on pg 3. Applicant urges that the specification thus teaches that extreme temperature is a type of abiotic stress that can be measured as discussed above (response pg 10-11).

This is not found persuasive. The comparison to wild-type plants should be recited in the claims. The references to "extreme temperature" on pg 1 do not provide a clear definition of the term. Thus, the phrase is not clearly defined. A comparison to wild-type or plants not

Art Unit: 1638

transformed with the nucleic acid encoding the virus-encoded transport protein would obviate this rejection.

Claim 29 is indefinite in its recitation of "derivative thereof". The manner in which the derivative varies from pr17 is unclear.

Applicant made no arguments with respect to a similar rejection of claim 14.

Claim 28 is indefinite in its recitation of "nucleic acid which encodes a virus-encoded transport protein". Does this mean the plant is being transformed with a virus or does it simply mean the nucleic acid encodes a viral transport protein?

Claim Rejections - 35 USC § 102

8. Claims 28-29 and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Lucas (WO 97/06669). The rejection is repeated for the reasons of record as set forth in the Office action mailed 5 September 2002, as applied to claims 10-14, 17-19, 23 and 27. Applicant's arguments filed 11 April 2003 have been fully considered but they are not persuasive.

Lucas teaches a method of producing tobacco plants by transformation with nucleic acids encoding the wild-type or mutant movement protein of tobacco mosaic virus (pg 23-30). The method involved testing the regenerated transgenic plants under extreme temperatures (pg 23, 28-29); the tested transgenic plant was "used" to produce a plant, itself. The plants showed essentially normal growth (pg 28). Because the method of producing these plants involves the same steps as the instantly claimed methods, Lucas inherently teaches a method of producing

Art. Unit: 1638

plants with increased tolerance of fungi, including *Phytophthora infestans*. The movement protein of tobacco mosaic virus would also be a "derivative of" p17.

Applicant urges that Lucas does not teach or suggest a method for production of plants with the claimed tolerances, nor does Lucas teach testing or producing a plant, plant line, plant part, or cell with the cited tolerance (response pg 11-12).

This is not found persuasive for the reason stated in the rejection above.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.
June 25, 2003



**AMY J. NELSON, PH.D.
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